

- (1) Within 30 days—
 - (i) A change of ownership;
 - (ii) Any adverse legal action; or
 - (iii) A change in practice location.
- (2) All other changes in enrollment must be reported within 90 days.

(e) *Reporting requirements for all other providers and suppliers.* Reporting requirements for all other providers and suppliers not identified in paragraphs (a) through (d) of this section, must report to CMS the following information within the specified timeframes:

- (1) Within 30 days for a change of ownership or control, including changes in authorized official(s) or delegated official(s);

- (2) All other changes to enrollment must be reported within 90 days.

(3) Within 30 days of any revocation or suspension of a Federal or State license or certification including Federal Aviation Administration certifications, an air ambulance supplier must report a revocation or suspension of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported:

- (i) Specific pilot certifications including but not limited to instrument and medical certifications.
- (ii) Airworthiness certification.

(f) *Maintaining and providing access to documentation.* (1)(i) A provider or a supplier that furnishes covered ordered items of DMEPOS, clinical laboratory, imaging services, or covered ordered/certified home health services is required to—

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered items of DMEPOS or clinical laboratory or imaging services) relating to written orders and certifications and requests for payments for items of DMEPOS and clinical lab-

oratory, imaging, and home health services.

(2)(i) A physician who orders/certifies home health services and the physician or, when permitted, other eligible professional who orders items of DMEPOS or clinical laboratory or imaging services is required to—

(A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and

(B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered the items of DMEPOS or the clinical laboratory or imaging services) relating to written orders or certifications or requests for payments for items of DMEPOS and clinical laboratory, imaging, and home health services.

[73 FR 69939, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008, as amended at 75 FR 24449, May 5, 2010; 75 FR 73628, Nov. 29, 2010; 77 FR 25318, Apr. 27, 2012]

§ 424.517 Onsite review.

(a) CMS reserves the right, when deemed necessary, to perform onsite review of a provider or supplier to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed for establishing compliance with conditions of participation. Based upon the results of CMS's onsite review, the provider may be subject to denial or revocation of Medicare billing privileges as specified in § 424.530 or § 424.535 of this part.

(1) *Medicare Part A providers.* CMS determines, upon on-site review, that the provider meets either of the following conditions:

- (i) Is unable to furnish Medicare-covered items or services.
- (ii) Has failed to satisfy any of the Medicare enrollment requirements.

(2) *Medicare Part B providers.* CMS determines, upon review, that the supplier meets any of the following conditions:

- (i) Is unable to furnish Medicare-covered items or services.
- (ii) Has failed to satisfy any or all of the Medicare enrollment requirements.
- (iii) Has failed to furnish Medicare covered items or services as required by the statute or regulations.
- (b) [Reserved]

[73 FR 66940, Nov. 19, 2008]

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, including applications for a new practice location, and any applications received in response to a revalidation request based on a CMS assessment of risk and assignment to a level of “limited,” “moderate,” or “high.”

(a) *Limited categorical risk—(1) Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as “limited” categorical risk:

- (i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.
- (ii) Ambulatory surgical centers.
- (iii) Competitive Acquisition Program/Part B Vendors.
- (iv) End-stage renal disease facilities.
- (v) Federally qualified health centers.
- (vi) Histocompatibility laboratories.
- (vii) Hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.
- (viii) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.
- (ix) Mammography screening centers.
- (x) Mass immunization roster billers
- (xi) Organ procurement organizations.

(xii) Pharmacies newly enrolling or revalidating via the CMS–855B application.

- (xiii) Radiation therapy centers.
- (xiv) Religious non-medical health care institutions.
- (xv) Rural health clinics.
- (xvi) Skilled nursing facilities.

(2) *Limited screening level: Screening requirements.* When CMS designates a provider or supplier as a “limited” categorical level of risk, the Medicare contractor does all of the following:

(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.

(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.

(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

(b) *Moderate categorical risk—(1) Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as “moderate” categorical risk:

- (i) Ambulance service suppliers.
- (ii) Community mental health centers.
- (iii) Comprehensive outpatient rehabilitation facilities.
- (iv) Hospice organizations.
- (v) Independent clinical laboratories.
- (vi) Independent diagnostic testing facilities.
- (vii) Physical therapists enrolling as individuals or as group practices.
- (viii) Portable x-ray suppliers.
- (ix) Revalidating home health agencies.
- (x) Revalidating DMEPOS suppliers.

(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a “moderate” categorical level of risk, the Medicare contractor does all of the following: